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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,123	07/30/2001	Natalie Samantha Delany	PG3606USW	9804
20462	7590	10/14/2004	EXAMINER	
SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939			ANDRES, JANET L	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,123

Applicant(s)

DELANY ET AL.

Examiner

Janet L. Andres

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 2,4,6-47 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,48,49 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/01</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1646

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II, VR3 polypeptides, in the reply filed on 26 July 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-51 are pending in this application. Claims 1, 3, 5, 48, 49, and 51 are under examination as they pertain to VR3 polypeptides. Claims 2, 4, 6-47, and 50 are withdrawn from consideration as being drawn to a non-elected invention.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (pp. 20 and 29). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 3, 48, and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. patent 6,239,267.

The '267 patent teaches a human vanilloid receptor; see column 9, lines 8-9, for example.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 3, 48, 49, and 51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptide of SEQ ID NO: 5 and that of the prior art, does not reasonably provide enablement for all human vanilloid receptors, all VR3 polypeptides, and variants thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to a genus, human vanilloid receptors and variants thereof, or for claims 3 and 51, hVR3 and variants thereof. There is no limitation as to the sequences of the encompassed polypeptides, and no requirement that the variants have any function. Thus the claims are broad in scope, and encompass variants that need not have receptor activity. As opposed to the claims, what is disclosed is narrow: a single polypeptide with one disclosed function and no other obvious specific functions. Applicant has not described the characteristics of this polypeptide so that one of skill in the art could predictably identify other polypeptides that would have the same distinguishing characteristics. Applicant has not described the properties of the sequence that are required for a functional protein. Thus, the essential characteristics of vanilloid receptor proteins and of hVR3 proteins in particular are not described. Further, while recombinant techniques are available, it is not routine in the art to screen large numbers of

Art Unit: 1646

nucleic acids that might potentially encode such proteins where the expectation of obtaining similar activity is unpredictable. Thus one of skill in the art would require additional guidance, such as information as to what structural features would result in characteristic vanilloid receptor function or, for claims 3 and 51, characteristic hVR3 function, in order to practice the invention commensurate with the scope of the claims without undue experimentation.

7. Claims 48 and 49 are additionally rejected under 35 U.S.C. 112, first paragraph, as lacking enablement for the intended uses specified.

The specification teaches two human vanilloid receptors and teaches that they are capsaicin-activated calcium pumps. This is not sufficient guidance as to how they could be used to treat disorders, or to screen for agents useful in disease. There is no information as to how they are involved in any disorder. hVR3 is found in trachea, prostate, placenta, kidney, and pancreas. There is no guidance as to its particular role in these tissues, under what circumstances it is modulated, what the consequences of such modulation are, or what particular conditions it is involved in. There is further no information as to how this expression is associated with pain due to such disorders as rheumatoid arthritis or irritable bowel syndrome. Thus it would require undue experimentation for the artisan to use the proteins as claimed.

8. Claims 1, 3, 48, 49, and 51 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1646

The claims are drawn to polypeptides identified only as human vanilloid receptors or hVR3 proteins, and variants of these proteins with no requirement for any function for such variants. Such polypeptides could vary substantially in length and in composition, and could have very different structural and functional characteristics from the polypeptide of SEQ ID NO: 5. Applicant has not described any common characteristics linking these different polypeptides so that the skilled artisan could identify them as members of a genus. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. Since there are no required regions or functions, the claim limitations are not sufficient to impart either characteristic physical, structural or functional features to the invention. The skilled artisan thus cannot envision the detailed chemical structure of the encompassed genus of polypeptides, regardless of the complexity or simplicity of the method of isolation.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 3, 5, 48, 49, and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 48, 49, and 51 are indefinite in the recitation of "variants". There is no definition of a "variant" in the specification; the artisan would be unable to determine what

Art Unit: 1646

degree of variation from the disclosed sequence would be encompassed, and thus what polypeptides Applicant intended the claims to encompass.

Claim 5 is indefinite in the reference to a figure, rather than to the identification number of an entered sequence. MPEP 2173.05(s) states,

Where possible, claims should be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted).

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 09/857,123

Page 7

Art Unit: 1646

Janet L. Andres, Ph.D.

12 October 2004



JANET ANDRES
PRIMARY EXAMINER